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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,442	07/24/2001	Samir S. Mitragotri	62803.000008	1231

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EXAMINER
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FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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08/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/868,442	<b>Applicant(s)</b> MITRAGOTRI ET AL.	
	<b>Examiner</b> JONATHAN ML FOREMAN	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 77-81,89,91-94,98 and 100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 89 and 100 is/are allowed.
- 6) ☒ Claim(s) 77-81,91-94 and 98 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/9/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 7/9/08 has been entered.

### *Information Disclosure Statement*

The information disclosure statement filed 7/9/08 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 77 – 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,587,705 to Kim et al. in view of U.S. Patent No. 4,151,832 to Hamer.

In reference to claims 77 - 79, Kim et al. disclose applicant's claimed invention including increasing a permeability level of an area of skin with low frequency ultrasound (Col. 10, lines 28 – 31; Col. 7, lines 4 – 5); extracting at least one analyte from the area of skin by application of a

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transport force (Col. 10, lines 47 – 53); receiving the analyte in a sensing zone in communication with the area (Col. 10, lines 51 – 52); and monitoring changes in the analyte concentration of the body fluid by continuously determining the quantity of the analyte in the sensing zone (Col. 10, lines 15 – 23). Kim et al. discloses the transport force being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces (Col. 10, lines 47 – 53), cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof. However, Kim et al. fail to disclose the transport force being a vacuum force and placing a mesh between the vacuum force and skin in order to maintain a surface configuration of the skin. Hamer discloses a method for analysis of an analyte in a body fluid including using a vacuum force generated by a mechanical means as a transport force and placing a mesh (6) between the vacuum force and skin in order to maintain a surface configuration of the skin (Col. 1, lines 66 – 68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method disclosed by Kim et al. to include including using a vacuum force and placing a mesh between the vacuum force and skin as taught by Hamer in order to obtain a desired sample and prevent the skin form being sucked in more than required (Col. 2, lines 6 – 7).

4. Claims 80 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,587,705 to Kim et al. in view of in view of U.S. Patent No. 4,767,402 to Kost et al. and U.S. Patent No. 6,059,736 to Tapper.

In reference to claims 80 and 98, Kim et al. disclose applicant's claimed invention including increasing a permeability level of an area of skin with low frequency ultrasound (Col. 10, lines 28 – 31; Col. 7, lines 4 – 5); extracting at least one analyte from the area of skin by application of a

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transport force (Col. 10, lines 47 – 53); receiving the analyte in a sensing zone in communication with the area (Col. 10, lines 51 – 52); and monitoring changes in the analyte concentration of the body fluid by continuously determining the quantity of the analyte in the sensing zone (Col. 10, lines 15 – 23). Kim et al. discloses the transport force being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces (Col. 10, lines 47 – 53), cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof. Kim et al discloses increasing a permeability level of an area of skin with low frequency ultrasound forces as low as 10 MHz, and states that lower frequencies may be used (Col. 17, lines 41 – 47). However, Kim et al. fails to disclose the frequency being less than 2.5 MHz. Kost et al. teaches the use of low frequency ultrasound forces less than 2.5 MHz to increase the permeability of skin (Col. 3, lines 26 – 29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the low level ultrasound frequency as disclosed by Kim et al. to be less than 2.5 MHz as taught by Kost et al. so as to avoid any significant temperature rise and destructive effect on skin (Col. 8, lines 5 – 8). Additionally, Kim et al. fail to disclose the transport force being an electrical force selected from the group consisting of iontophoretic forces, electrosmotic forces, electroporation forces or combinations thereof. However, Tapper teaches the use of electrical transport forces for withdrawing analytes selected from the group consisting of iontophoretic forces, electrosmotic forces, electroporation forces or combinations thereof (Col. 9, lines 65 – 66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Kim et al. to include the use of electrical transport forces for withdrawing analytes selected from the group consisting of iontophoretic forces, electrosmotic forces, electroporation forces or combinations

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thereof as taught by Tapper in order to provide a means for extremely accurate sample withdrawal (Col. 9, lines 8 – 9).

5. Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,587,705 to Kim et al. in view of in view of U.S. Patent No. 4,767,402 to Kost et al. and U.S. Patent No. 5,622,168 to Keusch et al.

In reference to claim 81, Kim et al. disclose applicant's claimed invention including increasing a permeability level of an area of skin with low frequency ultrasound (Col. 10, lines 28 – 31; Col. 7, lines 4 – 5); extracting at least one analyte from the area of skin by application of a transport force (Col. 10, lines 47 – 53); receiving the analyte in a sensing zone in communication with the area (Col. 10, lines 51 – 52); and monitoring changes in the analyte concentration of the body fluid by continuously determining the quantity of the analyte in the sensing zone (Col. 10, lines 15 – 23). Kim et al. discloses the transport force being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces (Col. 10, lines 47 – 53), cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof. Kim et al discloses increasing a permeability level of an area of skin with low frequency ultrasound forces as low as 10 MHz, and states that lower frequencies may be used (Col. 17, lines 41 – 47). However, Kim et al. fails to disclose the frequency being less than 2.5 MHz. Kost et al. teaches the use of low frequency ultrasound forces less than 2.5 MHz to increase the permeability of skin (Col. 3, lines 26 – 29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the low level ultrasound frequency as disclosed by Kim et al. to be less than 2.5 MHz as taught by Kost et al. so as to avoid any significant temperature rise and destructive effect on skin (Col. 8, lines 5 – 8). Additionally, Kim

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et al. fail to disclose applying a gel to the skin in order to encourage osmosis. However, Keusch et al. teach the use of applying a gel to the skin in order to encourage osmosis (Col. 20, line 64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the step of applying a gel to the skin to encourage osmosis as taught by Keusch et al. in order to cleanse the skin prior to sampling.

6. Claims 91 - 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,587,705 to Kim et al. in view of in view of U.S. Patent No. 4,767,402 to Kost et al. and U.S. Patent No. 6,562,014 to Lin et al.

In reference to claims 91 - 94, Kim et al. disclose applicant's claimed invention including increasing a permeability level of an area of skin with low frequency ultrasound (Col. 10, lines 28 – 31; Col. 7, lines 4 – 5); extracting at least one analyte from the area of skin by application of a transport force (Col. 10, lines 47 – 53); receiving the analyte in a sensing zone in communication with the area (Col. 10, lines 51 – 52); and monitoring changes in the analyte concentration of the body fluid by continuously determining the quantity of the analyte in the sensing zone (Col. 10, lines 15 – 23). Kim et al. discloses the transport force being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces (Col. 10, lines 47 – 53), cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof. Kim et al discloses increasing a permeability level of an area of skin with low frequency ultrasound forces as low as 10 MHz, and states that lower frequencies may be used (Col. 17, lines 41 – 47). However, Kim et al. fails to disclose the frequency being less than 2.5 MHz. Kost et al. teaches the use of low frequency ultrasound forces less than 2.5 MHz to increase the permeability of skin (Col. 3, lines 26 – 29). It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to modify the low level ultrasound frequency as disclosed by Kim et al. to be less than 2.5 MHz as taught by Kost et al. so as to avoid any significant temperature rise and destructive effect on skin (Col. 8, lines 5 – 8). Additionally, Kim et al. fail to disclose receiving the at least one analyte through absorption into a gel. However, Lin et al. disclose a method of sampling at least one analyte including receiving the at least one analyte through absorption into a gel (Col. 10, lines 12 – 15). The gel is considered to be an appropriate density immiscible fluid. The claim would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of receiving the at least one analyte through absorption into a gel as taught by Lin et al. to improve the sampling disclosed by Kim et al. for the predictable result of collecting a sample of a desired analyte.

#### ***Allowable Subject Matter***

7. Claims 89 and 100 are allowed.

#### ***Response to Arguments***

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736